Docket No. CRD-5051USNP

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Hikmat Hojeibane et al.	Confirmation No.:	2568
Serial No.	:	10/699,295		
Filed	:	October 31, 2003		
Title	:	IMPLANTABLE VALVULAR PROSTHESIS		
Art Unit	:	3738		
Examiner	:	Brian Pellegrino		

MAIL STOP APPEAL BRIEF PATENTS
Commissioner for Patents
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APPEAL BRIEF

i. Real Party in Interest

The real party of interest is Cordis, a Florida Corporation.

ii. Related Appeals and Inferences

There are no related appeals and inferences known to the Applicants.

iii. Status of Claims

Claims 1-33 are pending in the case. Claims 1-22, 24, 27-29, 32, and 33 have been finally rejected on Feb. 13, 2007 and this Appeal is taken from these claims. Claims 23, 25, 26, 30, and 31 have been withdrawn from consideration on Feb. 13, 2007.

iv. Status of Amendments

A Final Office Action rejecting Claims 1-22, 24, 27-29, 32, and 33, and withdrawing Claims 23, 25, 26, 30, and 31 from consideration was mailed on Feb. 13, 2007. A Notice of Appeal was filed on May 14, 2007 in response thereto. No amendment has been filed subsequent to the final rejection.

v. Summary of Claimed Subject Matter

Independent Claim 1 of the present application is directed towards a medical device, and in particular, to a stent-based prosthetic valve. The valve includes a radially expandable structural frame defining a longitudinal axis. *Application* p. 11, lines 18-20. The structural frame is comprised of an anchor structure, p. 23, lines 5-16, a connecting member, p. 11, lines 18-24, and a cantilever strut, p. 12, line 1 – p. 16, line 3. *See* Figures **2A** (reproduced in **Figure Appendix I**). The anchor structure, connecting member, and cantilever strut all have first and second ends, with the anchor structure having first and second open ends. The second end of the anchor structure is directly attached to the first end of the connecting member, and the second end of the connecting member is cooperatively associated with the first end of the cantilever strut. *See* Figures **2A**. Claim 1 also includes a biocompatible membrane assembly having a substantially tubular configuration with a first open and a second closed end, p. 10, lines 17-22. *See* Figure **1A** (reproduced in **Figure Appendix I**). The first end of the membrane assembly is attached along the second end of the cantilever valve strut. *See* Figure **1A**.

Independent Claim 32 of the present application is also directed towards a medical device, and in particular, to a stent-based prosthetic valve. The valve includes a radially expandable anchor structure, p. 23, lines 5-16, which is formed from a lattice of interconnected elements, p. 23, line 5 – p. 24, line 20. *See* Figures **3A** (reproduced in **Figure Appendix I**). The anchor structure has a substantially cylindrical configuration with first and second open ends, and defines a longitudinal axis and longitudinal direction that extends there between. The valve also includes a connecting member having first and second ends. p. 11, lines 18-24. The first end of the connecting member is directly attached to the second end of the anchor structure. *See* Figure **2A**. The valve further includes a cantilever valve strut having first and second ends. p.

12, line 1 – p. 16, line 3. The first end of the cantilever valve strut is cooperatively associated with the second end of the connecting member. *See* Figure **2A**. Finally, the valve includes a biocompatible membrane assembly having a substantially tubular configuration. p. 10, lines 17-22. The biocompatible membrane assembly has a first open and a second closed end with the first end of the membrane assembly attached along the second end of the cantilever valve strut. *See* Figure **1A**.

Independent Claim 33 of the present application is also directed towards a medical device, and in particular, to a stent-based prosthetic valve. The valve includes a radially expandable anchor structure, p. 23, lines 5-16, which is formed from a lattice of interconnected elements, p. 23, line 5 – p. 24, line 20. *See* Figures **3A**. The anchor structure has a substantially cylindrical configuration with first and second open ends, and defines a longitudinal axis and longitudinal direction that extends there between. The valve also includes a collar located proximal to the radially expandable anchor. p. 37, line 15 – p. 38, line 16. *See* Figure **6A** (reproduced in **Figure Appendix I**). The valve further includes a connecting member having first and second ends. p. 11, lines 18-24. The first end of the connecting member is directly attached to the second end of the anchor. The second end of the connecting member is directly attached to the proximal collar. The valve also includes a cantilever valve strut having first and second ends. p. 12, line 1 – p. 16, line 3. The first end of the cantilever strut is attached to the proximal collar. The cantilever valve strut extends in the distal direction substantially parallel to the longitudinal axis. Finally, the valve includes a biocompatible membrane assembly having a substantially tubular configuration. p. 10, lines 17-22. The biocompatible membrane assembly has a first open and a second closed end, with the first end being attached along the second end of the cantilever valve strut.

vi. **Grounds of Rejection to Be Reviewed on Appeal**

1. Claims 1-3, 5, 6, 8, 9, 22, 24, 27-29, 32, and 33 stand finally rejected under 35 U.S.C. § 103(a) as being anticipated by Pavcnik et al. (U.S. Patent No. 5,200,336) in view of Pinheiro (U.S. Patent No. 6,355,056).
2. Claim 4 stands finally rejected under 35 U.S.C. § 103(a) as being anticipated by Pavcnik et al. (U.S. Patent No. 5,200,336) in view of Pinheiro (U.S. Patent No. 6,355,056) and further in view of Huter et al. (U.S. Patent No. 6,511,496).

3. Claim 7 stands finally rejected under 35 U.S.C. § 103(a) as being anticipated by Pavcnik et al. (U.S. Patent No. 5,200,336) in view of Pinheiro (U.S. Patent No. 6,355,056) and further in view of Quijano et al. (U.S. Patent No. 5,500,014).
4. Claims 10, 12-21 stand finally rejected under 35 U.S.C. § 103(a) as being anticipated by Pavcnik et al. (U.S. Patent No. 5,200,336) in view of Pinheiro (U.S. Patent No. 6,355,056) and further in view of Alt et al. (U.S. Patent No. 5,788,979).
5. Claim 11 stands finally rejected under 35 U.S.C. § 103(a) as being anticipated by Pavcnik et al. (U.S. Patent No. 5,200,336) in view of Pinheiro (U.S. Patent No. 6,355,056) and further in view of Kónya et al. (U.S. Patent No. 6,368,338).

vii. Argument

The Examiner has finally rejected independent Claims 1, 32, and 33 under 35 U.S.C. § 103(a) for being anticipated by Pavcnik et al. (U.S. Patent No. 5,200,336) in view of Pinheiro (U.S. Patent No. 6,355,056). However, Pavcnik in view of Pinheiro fails to disclose each of the claim limitations recited by independent Claims 1, 32, and 33. Further, there is no reasonable suggestion or motivation for one skilled in the art to meaningfully combine the teachings of Pavcnik and Pinheiro to construct the claimed invention. For these reasons, the Applicants respectfully assert that Pavcnik in view of Pinheiro is not an appropriate basis for rejection under 35 U.S.C. § 103(a). The Applicants respectfully maintain that independent Claims 1, 32, and 33 are in condition for allowance and accordingly request that the rejections to these claims be overruled.

As Claims 2, 3, 5, 6, 8, 9, 22, 24, 27, 28, and 29 depend directly or indirectly upon independent Claim 1, the Applicants respectfully request that the rejection of these claims be overruled as well. Further, the Applicants assert that the Claim 1 is an allowable generic claim linking Claims 23, 25, 26, 30, and 31. As a result, the Applicants respectfully request that these claims be reinstated and allowed.

The Examiner has also rejected dependent Claims 4, 7, and 11 as being anticipated by Pavcnik in view of Pinheiro and in further view of Huter et al. (U.S. Patent No. 6,511,496), Quijano et al. (U.S. Patent No. 5,500,014), and Kónya et al. (U.S. Patent No. 6,368,338), respectively. Claims 10 and 12-21 were rejected as being anticipated by Pavcnik in view of

Pinheiro and in further view of Alt et al. (U.S. Patent No. 5,788,979). The Applicants respectfully maintain that there is no reasonable motivation for one with ordinary skill in the art to combine Pavcnik in view of Pinheiro with any of these references. Moreover, because each claim depends directly or indirectly upon independent Claim 1 and Pavcnik in view of Pinheiro fails to disclose each of the claim limitations within independent Claim 1, the Applicants respectfully request that the rejection of these dependent claims be overruled.

I. CLAIMS 1, 32, AND 33 STAND FINALLY REJECTED UNDER 35 U.S.C. § 103(a) AS BEING ANTICIPATED BY PAVCNIK ET AL. (U.S. PATENT NO. 5,200,336) IN VIEW OF PINHEIRO (U.S. PATENT NO. 6,355,056). APPLICANTS RESPECTFULLY TRAVERSE AND THE REJECTION SHOULD BE OVERRULED.

A. Examiner Has Not Proffered a Prior Art Combination that Accounts for Each Limitation Within Claim 1, 32, or 33.

In order to establish a *prima facie* case of obviousness, the Examiner must identify some combination of prior art references that teaches or suggests every claim limitation. MPEP § 2143. The Examiner has not satisfied this burden with regard to independent Claims 1, 32, and 33. Accordingly, the Applicants respectfully maintain that Pavcnik in view of Pinheiro does not anticipate Claim 1, 32, or 33 of the present application, and request that the rejections to those claims be overruled.

1. Pavcnik in view of Pinheiro does not disclose a biocompatible membrane having a substantially tubular configuration with a first open and a second closed end, as required by Claims 1, 32, and 33.

When judging the patentability of a claim against what is disclosed in the prior art, each and every word within the claim must be considered. *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970). Independent Claims 1, 32, and 33 describe and claim a biocompatible membrane assembly having a substantially tubular configuration about the longitudinal axis with a first open and a second closed end. The Examiner proffers covering **45** of Pavcnik, specifically the embodiment depicted within Pavcnik Figure **17** (reproduced in **Figure Appendix II**), as a biocompatible membrane having a substantially tubular configuration. In addition to mischaracterizing Pavcnik covering **45** as a tubular structure, the Examiner has failed to affirmatively identify any element within covering **45** that satisfies the further requirement of

having an open and a closed end. This omission is contrary to the requirements set forth by MPEP § 2143.

More importantly, covering **45** does not comprise any features satisfying the claim limitation of having a substantially tubular configuration with a first open and a second closed end. During examination, claims must be interpreted as broadly as their terms reasonably allow. MPEP § 2111.01. In particular, "[o]rdinary, simple English words whose meaning is clear and unquestionable, absent any indication that their use in a particular context changes their meaning, are construed to mean exactly what they say." *Chef Am., Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1372 (Fed. Cir. 2004). Thus, "tubular" is defined according to the plain meaning of the term. While the modifier "substantially" certainly does broaden the term to some degree, it cannot be allowed to negate the meaning of the word it modifies. *Arvin Industries, Inc. v. Berns Air King Corp.*, 525 F.2d 182, 185 (7th Cir. 1975). Along these guidelines, "tubular" is generally understood as having the form of a tube, with tube being defined as a hollow structure that conveys fluid or functions as a passage, or alternately the hollow, three-dimensional form created when taking a closed, fixed perimeter and extruding this form along a perpendicular axis. *The American Heritage Dictionary of the English Language* (New College Edition 1976). Independent Claims 1, 32, and 33 further impose the limitation that this tubular membrane assembly must have a first open and a second closed end.

The membrane assembly disclosed in the present application is made from a flexible, biocompatible material that is shaped into a tubular structure with a first open and a second closed end. *See Application* p. 27, lines 1-3. According to the specification, an exemplary embodiment could include a cup or cone shaped tube with a circular cross-section. *See* p. 27, lines 3-4, *and* Figure **1A** (Element **102**).

In contrast, Pavcnik does not disclose a membrane assembly having a substantially tubular configuration with a first open and a second closed end. Instead, Pavcnik discloses a twisted wire frame device that can be functionalized for a number of intravenous medical applications, such as for use as an occlusion device, *see Pavcnik* col. 6, lines 2-6, *and* Figure **16** (reproduced in **Figure Appendix II**), a simple valve, *see* col. 5, lines 39-42, *and* Figures **13-14** (reproduced in **Figure Appendix II**), and two different types of stents, *see* col. 6, lines 15-17, *and* Figures **17**, **18** (reproduced in **Figure Appendix II**). In each embodiment, a biocompatible covering **45** is used to achieve different results. The Examiner specifically alleges that the

covering embodiment depicted by Figure **17** is the equivalent of the biocompatible membrane **102** of the present application. However, none of the various coverings disclosed by Pavcnik, including that of Figure **17**, incorporate both an open and a closed end with a membrane having a substantially tubular configuration.

Figure **17** depicts a covering **45** that is stretched over a twisted wire frame **11** to create a three-dimensional saddle shape. *See* col. 6, lines 20-24. This structure lacks the compulsory interior surface area necessary for a structure to be described as hollow, and cannot be construed to enclose anything or serve as a conduit for liquid. Further, covering **45** in the embodiment depicted by Figure **17** "includes a central opening through which [a] graft prosthesis is placed and held in place." *Id.* Consequently, covering **45** of this embodiment lacks both open and closed ends, and instead has a central opening located at the longitudinal midline. *See* Figure **17**. Accordingly, cover **45** as depicted in Figure **17** does not satisfy either of the claim limitations within independent Claims 1, 32, and 33, requiring the membrane assembly to be substantially tubular with a first open and a second closed end.

Similarly, the covers depicted in other embodiments of Pavcnik do not satisfy the claim limitation of having a substantially tubular configuration, or a first open and a second closed end. For example, Figure **16** discloses that cover **45** is twisted into the same saddle shape of Figure **17** *supra*. For the same reasons that the embodiment depicted by Figure **17** cannot be described as tubular, the embodiment of cover **45** depicted by Figure **16** also cannot be described as tubular. Figure **16**'s cover **45** also does not incorporate an opening cut through its center, differentiating this embodiment from the one depicted in Figure **17**. *See* Figure **16**. Thus, covering **45** of this embodiment lacks both open and closed ends, and instead has a closed mid-region that is used to obstruct flow. *See* col. 6, lines 2-14.

The embodiments of cover **45** illustrated by Pavcnik Figures **13-14** also cannot be described as either tubular or having either open or closed ends as they are permutations of a flat cover sheet stretched across a flat surface. *See* col. 5, lines 30-42, *and* col. 6, lines 1-2. This sheet is used to passively flap in two directions to alternately allow and obstruct flow. *See* col. 5, lines 47-54.

Finally, Pavcnik Figure **18** does not disclose a biocompatible membrane having a substantially tubular configuration with a first open and a second closed end. Cover **45** of this embodiment forms the walls around a cylindrical stent graft. *See* col. 6, lines 30-35. While this

embodiment most closely resembles a membrane having a substantially tubular configuration, it comprises two open ends rather than a first open and a second closed end. Although the bottom half of the stent is not depicted within the figure, it is necessary for this end to be open if the device is to function as intended. *See* col. 6, lines 15-17. A stent is used to maintain an open passageway through a vessel. *See* col. 6, lines 30-35. A closed end would obstruct flow through the vessel, defeating the object and purpose of the apparatus. It therefore follows that even though Figure **18** depicts a substantially tubular assembly, it does not disclose a first open and a second closed end. Rather, Figure **18** discloses a tubular cover having two open ends.

Pinheiro discloses a tubular prosthesis that is similar to Pavcnik covering **45** as it is depicted in Figure **18**. Pinheiro tubular prosthesis **10** also forms the walls around a cylindrical stent graft. *See Pinheiro* col. 3, lines 21-34, *and* Figure **3** (reproduced in **Figure Appendix III**). Due to this equivalent functionality, Pinheiro tubular prosthesis **10** also comprises two open ends, rather than one open end and one closed end. Thus, neither Pavcnik nor Pinheiro, individually or in combination, discloses a biocompatible membrane structure having a first open and a second closed end. Accordingly, the Applicants respectfully request that the rejection of Claims 1, 32, and 33 be overruled.

2. Pavcnik in view of Pinheiro does not disclose a connecting member whose second end is cooperatively associated with the first end of a cantilever strut, as claimed in Claims 1 and 32.

Independent Claims 1 and 32 of the present application claim a connecting member whose second end is cooperatively associated with the first end of a cantilever strut. The Examiner purports to identify a connecting member and a cantilever valve strut within Pavcnik Figure **17**, but does not address the limitation of the present application regarding the relative orientation between these cooperatively associated elements.

The Examiner asserts that Pavcnik discloses a connecting member, barb **16**, which is connected to cantilever valve strut, frame **11**, through a third device, cannula **15**. However, it is clear from the Figure **17** that the cannula **15** affixes barb **16** to the *midpoint* of frame **11**. *See* Figure **17**. Assuming *arguendo* that the Examiner has correctly identified equivalent structures, this is a departure from the express claim limitation of the present application requiring the second *end* of the connecting member to be cooperatively associated with the first *end* of the cantilever strut. Even though one may argue that the difference is merely the relative orientation

between two cooperative elements, the Federal Circuit has warned against boiling down an invention to the "gist" or the "core" to find grounds to reject under 35 U.S.C. § 103(a), especially when this process results in disregarding express claim limitations. *Bausch & Lomb, Inc., v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 433, 449 (Fed. Cir. 1986). The Court criticized this form of analysis, describing it as superficial. *Id.* Further, this claim limitation cannot be found within Pinheiro, which does not disclose any elements that could be considered a cantilever. Pinheiro discloses instead two anchor stents that are connected by a series of connecting struts. *See* col. 2, lines 63-67.

For these reasons, the Applicants respectfully assert that neither Pavcnik nor Pinheiro, individually or in combination, satisfies the claim limitation of independent Claims 1 and 32 requiring the second end of the connecting member to be cooperatively associated with the first end of the cantilever strut. Accordingly, the Applicants respectfully request that the rejection to Claims 1 and 32 be overruled.

B. The Examiner Mischaracterized Several Elements of the Pavcnik Structure When Alleging that those Components Satisfy Specific Claim Limitations.

In addition to neglecting to address the key claim limitations discussed *supra*, the Examiner has mischaracterized several critical components of the Pavcnik structure. This misidentification has contributed to the mistaken assertion that the Pavcnik structure, when modified in view of Pinheiro, anticipates each of the claim limitations within the present application. The Applicants respectfully assert that these mischaracterizations are sufficient in themselves to warrant the overruling of the rejection to Claims 1, 32, and 33.

1. Pavcnik does not disclose a cantilever strut, as required by Claims 1, 32, 33.

Like the term "tubular", the term "cantilever" is ascribed with the generally understood definition of the term. *Chef Am., Inc.*, 358 F.3d at 1372. Along these guidelines, *The American Heritage Dictionary* defines cantilever as "a projecting beam or other structure supported only at one end." These structures are free to deflect at the extended free end of the member. E.A. Avallone & T. Baumeister III, *Mark's Standard Handbook for Mechanical Engineers* 277 (10th ed. 1996). These attributes are well accepted in the art and have been described extensively in

the field of mechanical engineering. *Id.* *See also* Myer Kutz, *Mechanical Engineer's Handbook* 510 (3d ed. 2005).

In accordance with these generally understood definitions, the cantilever valve struts **107** of the present application are projecting beams that are cooperatively associated with the connecting member **105**. In one embodiment, the cantilever valve strut **107** is fixed to and supported by proximal collar **108**. *See Application* Figure **2A**, *and* p. 12, lines 7-9. The second end of each projecting beam is free to deflect at the free end of the member. *See* p. 12, lines 5-7. This ability to deflect can be observed in Figures **4B** and **5B** (reproduced in **Figure Appendix I**), which show the valve assembly in the open and closed positions respectively. In the open position, the second end of each cantilever valve strut **107** can be seen deflecting radially inwards, towards the center of the vessel lumen. *See* Figure **4B**, *and* p. 34, lines 1-9. Conversely, in the closed position, the second end of each cantilever valve strut 107 can be seen deflecting radially outwards, towards the walls of the vessel lumen. *See* Figure **5B**, *and* p. 35, lines 13-21.

The Examiner has incorrectly alleged that Pavcnik frame **11** as depicted in Figure **17** is the equivalent of the cantilever valve strut **107** of the present invention. This is inconsistent with the generally understood definition of the term "cantilever". It is clear from the specification that what Pavcnik actually discloses is a bent frame created through the twisting of a piece of wire into a closed circumference. *See* col. 1, lines 55-58. The frame is fabricated from one continuous length of wire, depicted in Figure **19**, that is twisted into the saddle shape depicted in Figure **17**. *Id; see also* col. 3, lines 58-60. Consequently, each side length **13** of frame **11** is constrained as well as supported at both ends by an adjacent strut **13**.

According to the Pavcnik specification, a pair of frames **11** is used as stent adaptors **52** and **53**. These stent adaptors hold stent graft **75** in place within a damaged or diseased vessel. *See* col. 6, lines 18-20. Each strut of frame **11** is wedged against a vessel wall when in use. *See* Figure **17**. Nothing within frame **11** is projecting or protruding in a way that would satisfy the general definition associated with the term "cantilever". For that matter, the frame is also not supported at one end while being free to deflect at the other. Individual struts **13** also cannot qualify as cantilever struts because each side length strut **13** is supported at both ends. Unlike a cantilever, there is no free end to deflect.

Frame **11**, as stent adaptors **52** and **53**, is more akin to the anchor structure **104** of the present application in the sense that both are components that function to secure their respective devices to the wall of a vessel. *Compare Application* p. 26, lines 9-11, *with Pavcnik* col. 6, lines 18-24, *and* col. 6, lines 27-28. In this sense, what Pavcnik Figure **17** shows is a pair of anchor structures, **52** and **53**, connected by a connecting member, barb **16**.

For these reasons, the Applicants respectfully assert that the members cited by the Examiner as cantilever struts do not in fact qualify as cantilevers according to the generally understood definition of the term. These elements therefore do not satisfy the claim limitations of independent Claims 1, 32, and 33, which require a cantilever valve strut. The Applicants accordingly request that the rejection of these claims be overruled.

C. Claim 33 Was Rejected Based on the Combination of Two Incompatible and Disparate Entities.

Under MPEP § 2143.01, a conclusion of obviousness is not appropriate if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose. *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). In such a case, there is no suggestion or motivation to make the proposed modification. *Id.*

In rejecting independent Claims 1, 32, and 33, the Examiner begins by identifying an anchor structure depicted by Pavcnik Figure **18**, but then shifts focus onto Figure **17** to identify the other major structural components of the present application, namely the collar, connecting member, cantilever valve strut, and biocompatible membrane assembly. *See Office Communication* p. 2 (mailed Feb. 13, 2007). However, the devices depicted by these two figures, even though part of the same reference, are separate and distinct – each embodiment works in a different manner, and both are incompatible with each other.

The Examiner implicitly makes a conclusion of obviousness when rejecting Claim 33 based on the combination of these two independent devices within the same reference. Even though the two embodiments are based on the same foundation structure, the combination of the Pavcnik devices depicted in Figure **17** and Figure **18** would create a nonsensical amalgamation that renders the structural and functional contribution of the device depicted in Figure **18** functionally redundant and vestigial. In other words, by literally combining the devices depicted in Pavcnik Figures **17** and **18** as the Examiner suggests, the device **10** depicted by Pavcnik

Figure **18** would not function as intended. Further, if the device **10** shown in Figure **18** were substituted for the first stent adaptor **52** in Figure **17**, there would be no proximal or distal support for graft prosthesis **54**. According to the Pavcnik specification, the stated purpose for stent adaptor **52** is to hold the graft prosthesis **54** in place and provide a means to prevent blood from flowing around the prosthesis rather than through it. *See* col. 6, lines 20-27. The Pavcnik device depicted in Figure **18** serves a completely different purpose than stent adaptor **52**, as depicted in Figure **17**. Instead, the device **10** depicted in Figure **18** is akin to the graft prosthesis, but directly holds and seals the outer sleeve **64** to the vessel wall. For this reason, it is not designed to centrally support a member coming through its lumen, or obstruct perimeter flow. If the device depicted by Figure **18** of Pavcnik were used instead of stent adaptor **52**, such a substitution would impair the functionality of graft prosthesis **54**. Taken altogether, these results are contraindications that the embodiments should be combined.

It is impermissible for the Examiner to disregard or discount these details when identifying elements from disparate embodiments in order to account for the claim limitations within an application. The Federal Circuit has approved the notion that it is impermissible for an examiner to "pick and choose from a reference only so much of it as will support a given position, to the exclusion of other parts necessary to the full appreciation of what such reference fairly suggests to one of ordinary skill in the art." *Bausch & Lomb*, 796 F.2d at 448 (quoting *In re Wesslau*, 353 F.2d 238, 241 (CCPA 1965)). This requirement is also reflected in the MPEP where it specifies "a prior art reference must be considered in its entirety." MPEP § 2141.03. *See, e.g., W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540 (Fed. Cir. 1983). Consequently, Applicants respectfully assert that the Rejection of Claim 33 should be overruled.

D. There is No Suggestion or Motivation to Combine the Teachings of the Pavcnik and Pinheiro References.

To support a *prima facie* case of obviousness, the Examiner must demonstrate that there is some suggestion or motivation to modify a reference or combine reference teachings. MPEP § 2142. Further, "the mere fact that references *can* be combined or modified does not render the resultant combination obvious unless the prior art also *suggests* the desirability of the combination." MPEP § 2143.01 (emphasis added). *See e.g., In re Fritch*, 972 F.2d 1260 (Fed. Cir. 1992); *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990). It is impermissible for an Examiner to

state, without more, that the claimed invention could have been made by a person having ordinary skill in the art solely because each aspect of the invention was individually known in the art. MPEP § 2143.01. To establish a *prima facie* case of obviousness, the Examiner must point to some objective reason to combine the teachings of the references. *See e.g.*, *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Infer. 1993).

The Examiner merely states "it would have been obvious to one of ordinary skill in the art to place the connecting member at the second end of the anchor structure as taught by Pinheiro with the prosthetic valve device of Pavcnik et al. such that it ensures that it will not migrate." *See Office Communication* p. 3 (mailed Feb. 13, 2007). Firstly, Applicants respectfully assert that the Examiner meant to describe the Pavcnik device as a "stent graft", as the embodiment that the Examiner refers to is not a valve. *See* Pavcnik col. 6, lines 15-18. Finally, the Examiner does not indicate why one of ordinary skill in the art would want to directly attach the frame structure **11** to rod **16** to prevent migration when the connection via cannula **15** serves equally well to prevent any migration. In other words, the prior art does not suggest the desirability of a direct attachment or whether any benefit can be expected from such attachment. Accordingly, the Applicants respectfully contend that the Examiner has not proffered a valid explanation for combining the Pavcnik and Pinheiro references that is consistent with MPEP § 2142. As a result, the Examiner has not made out a *prima facie* case for obviousness and the Rejection to Claims 1, 32, and 33 should be overruled.

II. CLAIMS 2-22, 24, 27, 28, AND 29 STAND FINALLY REJECTED UNDER 35 U.S.C. § 103(a) AS BEING ANTICIPATED BY PAVCNIK ET AL. (U.S. PATENT NO. 5,200,336) IN VIEW OF PINHEIRO (U.S. PATENT NO. 6,355,056). APPLICANTS RESPECTFULLY TRAVERSE AND THE REJECTION SHOULD BE OVERRULED.

A. The Rejection of Claims 2-22, 24, 27, 28, and 29 Should Be Overruled Because Each Claim Depends Directly or Indirectly from Independent Claim 1, and Pavcnik in View of Pinheiro Does Not Account for Each of the Claim Limitations Within Claim 1.

According to MPEP § 2143.03, a dependent claim is nonobvious under 35 U.S.C. § 103 if it is derived from an independent claim that is found to be nonobvious. *See also In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988). Because Pavcnik in view of Pinheiro does not account for each claim limitation within Claim 1, the same cannot account for each claim limitation of the

dependant claims that derive from Claim 1. Accordingly, the Applicants respectfully request that the Rejection of Claims 2-22, 24, 27, 28, and 29 be overruled.

B. Claim 11 Stands Finally Rejected under 35 U.S.C. § 103(a) as Being Anticipated by Pavcnik in View of Pinheiro and Further in View of Kónya et al. (U.S. Patent No. 6,368,338). Applicants Respectfully Traverse and the Rejection Should Be Overruled.

1. Kónya does not teach a membrane having reinforcement structural fibers.

Claim 11 describes and claims a valve membrane having reinforcement fibers to further add support to the membrane. The Examiner contends that Kónya teaches this use of fibers, and that this teaching is combinable with Pavcnik in view of Pinheiro. However, the Applicants respectfully assert that Kónya does not actually teach the use of reinforcement fibers to add supplemental support to a membrane assembly. On the contrary, Kónya teaches the use of polyester fibers to promote thrombosis.

Kónya discloses an occlusion device that is used for occluding a vessel. This device, depicted in Figure **1**, comprises elastically deformable members **12** and jacket **16**. In the specification section cited by the Examiner (col. 12, lines 23-31), polyester threads are used as an occluding agent **20** to facilitate quicker occlusion by providing more sites for thrombosis to occur. *See* col. 12, lines 16-19. *See also* Figure **11**. Thus, the polyester fibers in Kónya were not used for the purpose of reinforcing a membrane. The polyester threads are not reinforcement fibers, and particularly not reinforcement fibers contained in a synthetic membrane that is used as a valve. Accordingly, Kónya cannot teach that fibers may be used for structurally reinforcing a membrane when Kónya itself uses polyester fibers in a completely different manner.

For this reason, Pavcnik in view of Pinheiro and in further view of Kónya does not teach all of the claim limitations of dependent Claim 11. Accordingly, the Applicants respectfully request that the Rejection to Claim 11 be overruled.

2. There is no suggestion or motivation to combine the teachings of Kónya with those of Pavcnik in view of Pinheiro.

A rejection under 35 U.S.C. § 103(a) requires the Examiner to make a factual showing that the claimed subject matter, as a whole, would have been obvious to a person of ordinary skill in the art. MPEP § 2142. It is the Examiner's affirmative duty to show such a teaching in the art. *Id.* The Applicants respectfully assert that the Examiner has not met his burden under 35 U.S.C. § 103(a).

The Examiner merely states that Kónya teaches that a filtering device can include reinforcement or structural fibers, and that it would have been obvious to use reinforcement fibers as taught by Kónya with the membrane of Pavcnik such that it strengthens the apparatus and prevents collapse. The Examiner has not made an affirmative showing that the two references *should* be combined.

Further, the Applicants assert that the Kónya reference is not appropriately combinable with Pavcnik in view of Pinheiro. Pavcnik discloses a prosthetic stent device that is used to open up and maintain passageways through vessels such that fluid may flow freely through. Kónya discloses a device that serves the complete opposite function. It teaches an occlusion method and apparatus for completely blocking flow within a vessel. The devices serve completely different functions and are fundamentally different devices. Applicants assert that Pavcnik in view of Pinheiro is not properly combinable with Kónya for a rejection under 35 U.S.C. § 103(a). Accordingly, the Applicants respectfully request that the Rejection of Claim 11 be overruled.

C. Rejection of Claim 27 was Improper Because Pavcnik in View of Pinheiro Does Not Disclose a Membrane with a Substantially Constant Diameter from the First End to the Second End.

Examiner refers to Pavcnik Figure **17** when purporting to identify a biocompatible membrane having a substantially tubular configuration about the longitudinal axis. As Applicants have discussed *supra*, describing the membrane as tubular unacceptably distorts the plain meaning of the term "tubular". In the same manner, it is inappropriate to describe the membrane as having a substantially constant diameter from the first end to the second end. The Pavcnik membrane of Figure **17** does not have any sort of opening or profile that resembles a

diameter that can be measured across a length. Therefore, Pavcnik in view of Pinheiro does not disclose a membrane with a substantially constant diameter from the first end to the second end.

The Examiner further asserts that "[o]ne of ordinary skill in the art … would have expected the Applicant's invention to perform equally well with the profile of the membrane taught by Pavcnik [Figure **17**] or the claimed 'substantially constant diameter' profile in claim(s) 27 because both membranes perform the same function of controlling blood flow." *See Office Communication*, p. 3 (mailed Feb. 13, 2007). The Applicants assert that this statement is erroneous and misleading. Contrary to the Examiner's assurances, the cover **45** taught by Pavcnik in Figure **17** would not perform equally as well as the disclosed membrane in the present application predominantly because the Pavcnik cover **45** is not a tubular structure with an open end and a closed end as discussed *supra*. Instead, it is a three-dimensional saddle shaped structure. *See* Figures **16**, **17**. The claimed invention functions largely through the ability of the membrane to capture and engorge with liquid when fluid flows through its first opening, and then release that liquid when flow is in the other direction. Because the Pavcnik covering **45** does not include an interior space with which to enclose fluid, it would not function in the same manner as the membrane of the present application.

Pavcnik Figure **18** does disclose a cover structure with a substantially constant diameter. However, even if the Examiner had intended to refer to the Pavcnik cover depicted in Figure **18**, this embodiment would still not satisfy the claim limitations of independent Claim 1, upon which Claim 27 depends. Figure **18**'s cover **45** is lacking a closed end, discussed *supra*, and the overall structure lacks further components, including a connecting member and a cantilever strut.

For these reasons, the Applicants respectfully assert that Claim 27 is not obvious in light of Pavcnik in view of Pinheiro, and that the Rejection to it should be overruled.

D. Rejection of Claim 28 was Improper Because Pavcnik in View of Pinheiro Does Not Disclose a Membrane with a Substantially Conical Shape.

The Examiner contends that the cover **45** structure of Pavcnik Figure **17** can be construed as having a substantially conical shape. *See Office Communication* p. 2 (mailed Feb. 13, 2007). Conical is defined as "shaped like a cone," with cone meaning "a surface generated by a straight line, the generator, passing through a fixed point, the vertex, and moving along the intersection with a fixed curve, the directrix." *American Heritage Dictionary*. Thus, the saddle-shaped cover

45 depicted in Figure **17** of Pavcnik cannot be construed as having a substantially conical shape consistent with the plain meaning of the term conical. For that matter, neither can the membrane depicted in Pavcnik Figure **18**. The Applicants respectfully maintain that Pavcnik in view of Pinheiro does not disclose a membrane with a substantially conical shape and accordingly request that the Rejection to Claim **28** be overruled.

III. CLAIMS 23, 25, 26, 30, AND 31 HAVE BEEN WITHDRAWN FROM CONSIDERATION PURSUANT TO 37 CFR § 1.142(b) AS NOT BEING DRAWN TO A GENERIC CLAIM. APPLICANTS RESPECTFULLY ASSERT THAT CLAIM 1 IS A VALID GENERIC CLAIM AND THE CLAIMS SHOULD BE REINSTATED.

The Applicants assert that Claim 1 is an allowable generic claim linking Claims 23, 24, 26, 30, and 31. The Applicants respectfully request that these Claims be reinstated and allowed.

IV. CONCLUSION

Because Pavcnik et al. in view of Pinheiro fails to disclose each of the elements recited by independent Claims 1, 32, and 33, Applicants respectfully contend that this combination should not be the basis for a rejection under 35 U.S.C. § 103(a). Accordingly, Applicants respectfully request that the Examiner withdraw the rejection of independent Claims 1, 32, and 33. As Claims 2-3, 5, 6, 8, 9, 22, 24, 27, 28 and 29 depend directly or indirectly upon Independent Claim 1, Applicants respectfully request that the rejection to those be overruled as being anticipated under Pavcnik et al. in view of Pinheiro under 35 U.S.C. § 103(a). Further, Applicants assert that the Claim 1 is an allowable generic claim linking Claims 23, 25, 26, 30, and 31. Applicants respectfully request the Examiner to reinstate and allow these claims.

Claims 4, 7, 10, 11, and 12-21 should be allowed because they each depend on Claim 1, which Applicants respectfully assert is an allowable independent claim. Further, the rejection to Claim 11 should be overruled because the Kónya does not teach a membrane having reinforcement structural fibers, and there is no suggestion or motivation to combine the teachings of Kónya with those of Pavcnik in view of Pinheiro. Finally, Claims 27 and 28 should be

allowed because Pavcnik in view of Pinheiro does not disclose a membrane that has a substantially constant diameter, nor does it disclose a substantially conical membrane.

Respectfully submitted,
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Reg. No. 47,072
Attorney for Applicants

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One Johnson & Johnson Plaza
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DATE: July 16, 2007

viii. Claims Appendix

1. (Previously Presented) A prosthetic valve comprising:

a radially expandable structural frame defining a longitudinal axis, including an anchor structure having first and second open ends, a connecting member having first and second ends, the first end of the connecting member being directly attached to the second end of the anchor structure, and a cantilever valve strut having first and second ends, the first end of the cantilever valve strut being cooperatively associated with the second end of the connecting member and the second end of the cantilever valve strut being free to deflect in at least a radial direction from the longitudinal axis; and

a biocompatible membrane assembly having a substantially tubular configuration about the longitudinal axis, with a first open and a second closed end, the first end of the membrane assembly being attached along the second end of the cantilever valve strut.

2. (Original) The prosthetic valve of claim 1 wherein the anchor structure is formed from a lattice of interconnected elements, and has a substantially cylindrical configuration about the longitudinal axis.

3. (Original) The prosthetic valve of claim 1 wherein the structural frame comprises a material selected from the group consisting of stainless steel, tantalum, platinum alloy, niobium alloy, cobalt allow, and nickel-titanium alloy.

4. (Original) The prosthetic valve of claim 1 wherein the structural frame comprises a polymer.

5. (Original) The prosthetic valve of claim 1 wherein the biocompatible membrane assembly is formed from a flexible membrane-like material.

6. (Original) The prosthetic valve of claim 5 wherein the membrane-like material is a biological material.

7. (Original) The prosthetic valve of claim 6 wherein the biological material is a vein.

8. (Original) The prosthetic valve of claim 7 wherein the membrane-like material is a synthetic material.

9. (Original) The prosthetic valve of claim 8 wherein the synthetic material is an elastomeric polymer.

10. (Original) The prosthetic valve of claim 8 wherein the synthetic material is a bioabsorbable material.

11. (Original) The prosthetic valve of claim 8 wherein the synthetic material further comprises a reinforcement fiber.

12. (Original) The prosthetic valve of claim 1 wherein at least a portion of the structural frame is coated with an agent.

13. (Original) The prosthetic valve of claim 12 wherein the agent coating contains a therapeutic agent.

14. (Original) The prosthetic valve of claim 12 wherein the agent coating comprises a pharmaceutic agent.

15. (Original) The prosthetic valve of claim 12 wherein the agent coating comprises an agent-eluting layer.

16. (Original) The prosthetic valve of claim 1 wherein at least a portion o the membrane assembly is coated with an agent.

17. (Previously Presented) The prosthetic valve of claim 16 wherein the agent coating contains a therapeutic agent.

18. (Original) The prosthetic valve of claim 17 wherein the agent coating contains a pharmaceutic agent.

19. (Original) The prosthetic valve of claim 17 wherein the agent coating comprising an agent-eluting layer.

20. (Original) The prosthetic valve of claim 1 wherein at least a portion of the membrane is impregnated with a therapeutic agent.

21. (Original) The prosthetic valve of claim 1 wherein at least a portion of the membrane assembly is impregnated with a pharmaceutic agent.

22. (Original) The prosthetic valve of claim 1 wherein the connecting member is a substantially straight member oriented in a direction substantially parallel to the longitudinal axis.

23. (Withdrawn) The prosthetic valve of claim 1 wherein the connecting member has a substantially helical shape about the longitudinal axis.

24. (Original) The prosthetic valve of claim 1 wherein the cantilever valve strut is a substantially straight member oriented in a direction substantially parallel to the longitudinal axis.

25. (Withdrawn) The prosthetic valve of claim 1 wherein the cantilever valve strut has a substantially helical shape about the longitudinal axis.

26. (Withdrawn) The prosthetic valve of claim 1 wherein the cantilever valve strut has a substantially sinusoidal shape oriented in a direction substantially parallel to the longitudinal axis.

27. (Original) The prosthetic valve of claim 1 wherein the tubular biocompatible membrane has a substantially constant diameter from the first to the second end.

28. (Original) The prosthetic valve of claim 1 wherein the tubular biocompatible membrane has a substantially conical shape.

29. (Original) The prosthetic valve of claim 1 wherein the structural frame further comprising a proximal collar attached to the second end of the connecting member and first end of the cantilever valve strut.

30. (Withdrawn) The prosthetic valve of claim 29 wherein the structural frame further comprises a centering leg cooperatively associated with the proximal collar.

31. (Withdrawn) The prosthetic valve of claim 29 wherein the structural frame comprises a proximal anchor cooperatively associated with the proximal collar.

32. (Previously Presented) A prosthetic valve comprising:

a radially expandable anchor structure formed from a lattice of interconnected elements, and having a substantially cylindrical configuration with a first and a second open end and a longitudinal axis defining a longitudinal direction extending there between;

a connecting member having a first and a second end, the first end of the connecting member being directly attached to the second end of the anchor;

a cantilever valve strut having a first and a second end, the first end of the cantilever valve strut being cooperatively associated with the second end of the connecting member, and the second end of the cantilever valve strut being free to deflect in at least a radial direction from the longitudinal axis; and

a biocompatible membrane assembly having a substantially tubular configuration with a first open and a second closed end, the first end of the membrane assembly being attached to the cantilever valve strut along the second end of the cantilever valve strut.

33. (Previously Amended) A prosthetic valve comprising:

a radially expandable anchor structure formed from a lattice of interconnected elements, and having a substantially cylindrical configuration with a first and a second open end and a longitudinal axis defining a longitudinal direction extending there between;

a collar located proximal to the radially expandable anchor;

a connecting member having a first and a second end, the first end of the connecting member being directly attached to the second end of the anchor and the second end of the connecting member being directly attached to the proximal collar;

a cantilever valve strut having a first and a second end, the first end of the cantilever valve strut being attached to the proximal collar and the second end of the cantilever valve strut being free to deflect in at least a radial direction from the longitudinal axis, the cantilever valve strut extending in a distal direction substantially parallel to the longitudinal axis; and

a biocompatible membrane assembly having a substantially tubular configuration with a first open and a second closed end, the first end of the membrane assembly being attached to the cantilever valve strut along the second end of the cantilever valve strut.

ix. Evidence Appendix

None.

x. Related Proceedings Appendix

None.

xi. **<u>Figure Appendix I:</u> Reproduced Figures from the Present Application**

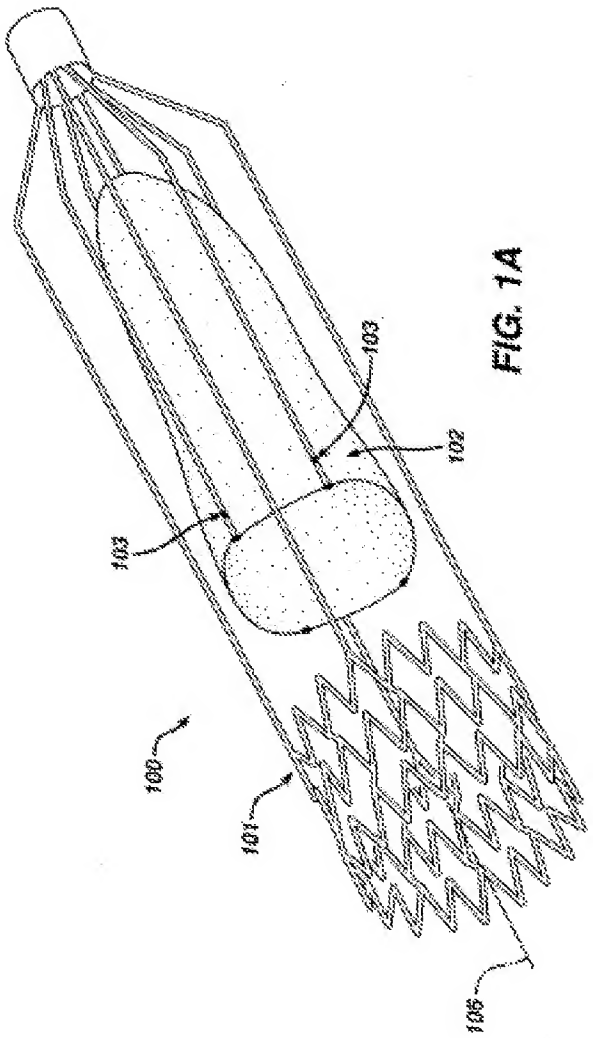

FIG. 1A

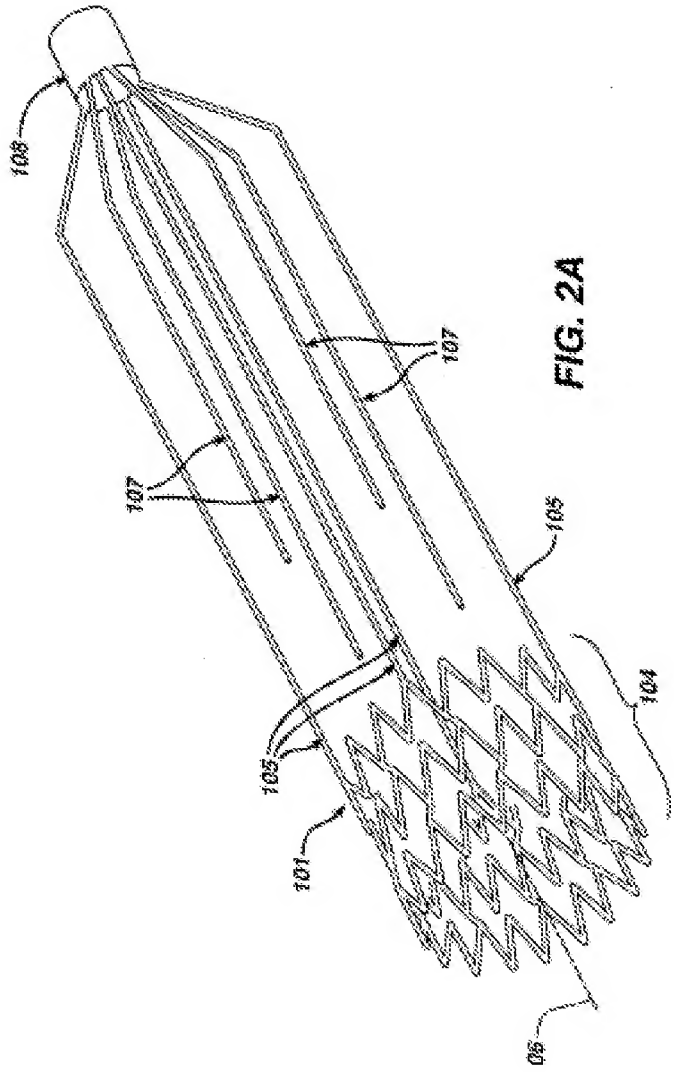
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FIG. 2A

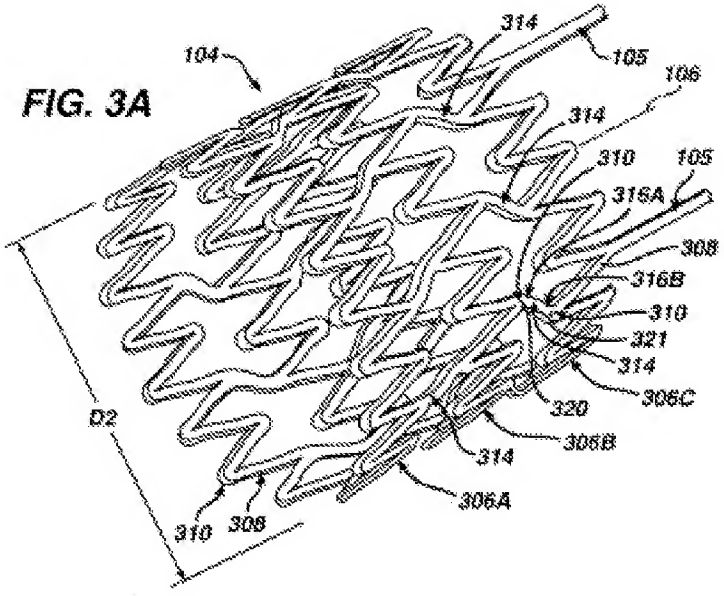
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FIG. 3A

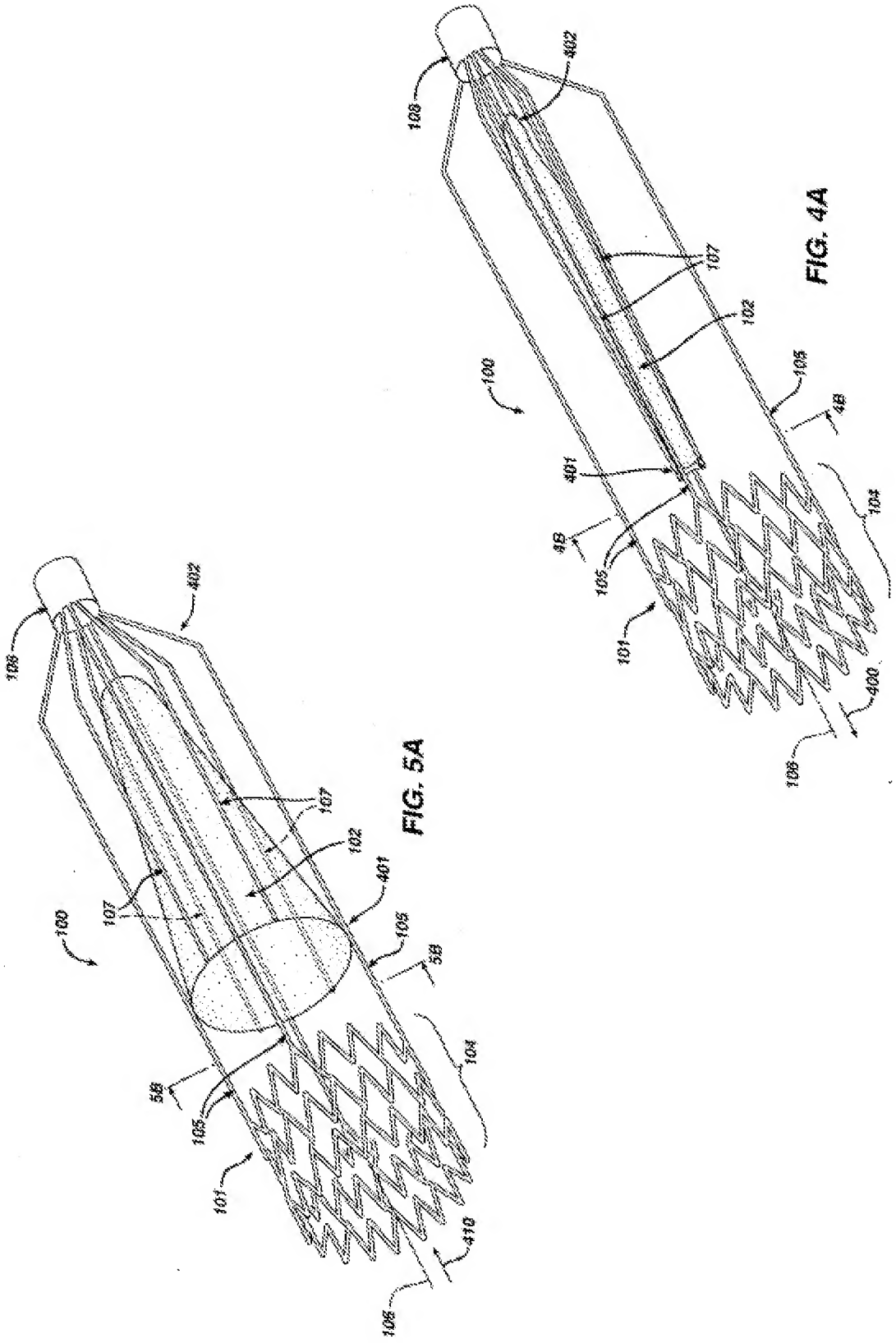
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FIG. 4A
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FIG. 5A

FIG. 4B

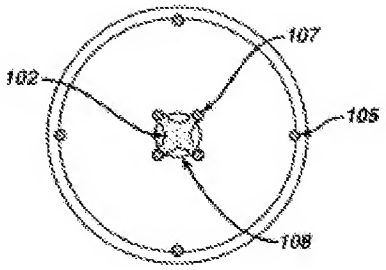
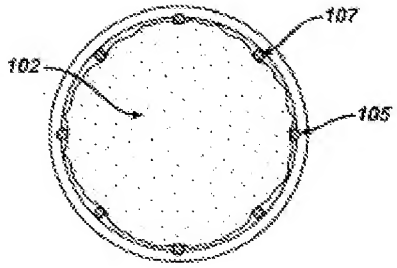


FIG. 5B



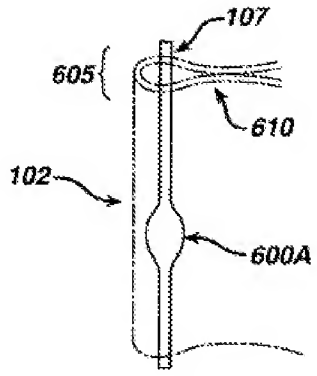


FIG. 6A

xii. **<u>Figure Appendix II:</u> Reproduced Pavcnik Figures**

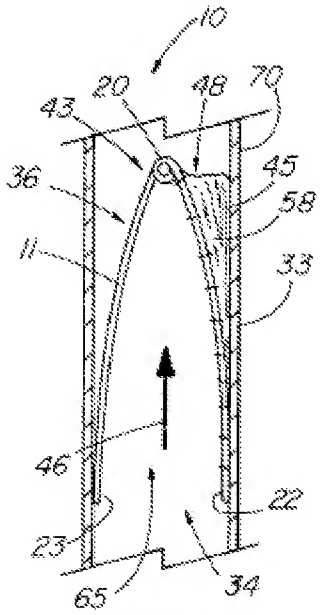


FIG. 13

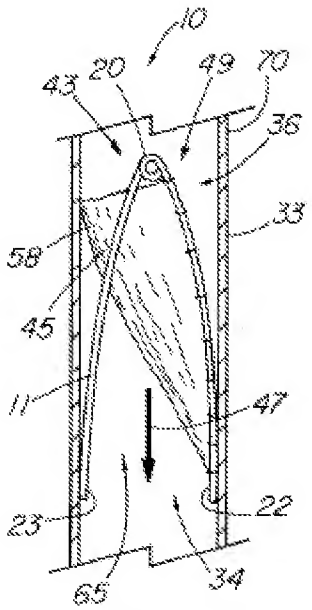


FIG. 14

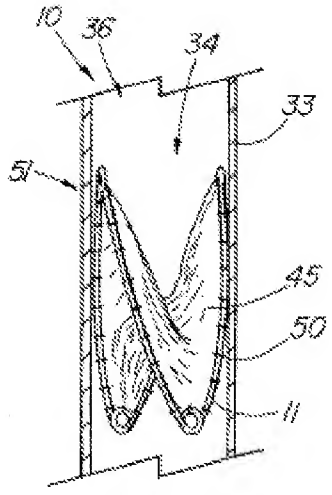


FIG. 16

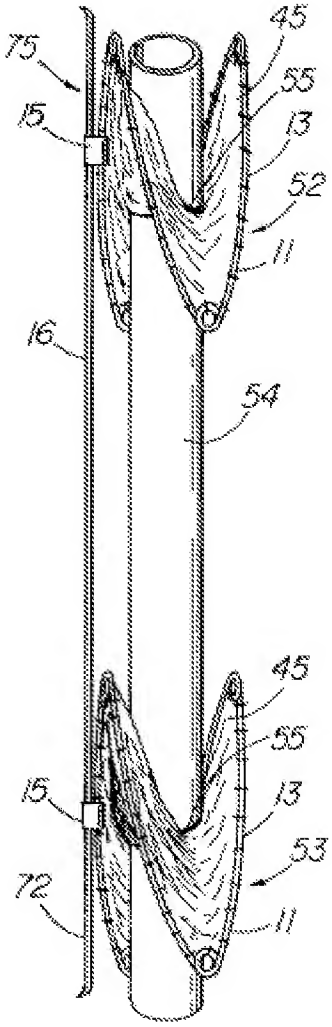

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FIG. 17

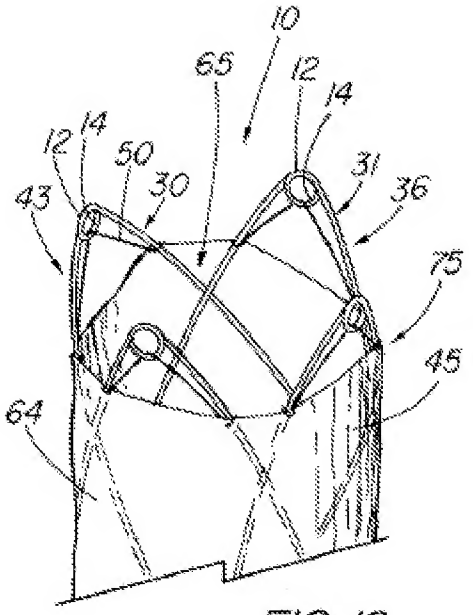
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FIG. 18

xiii. **<u>Figure Appendix III:</u> Reproduced Pinheiro Figures**

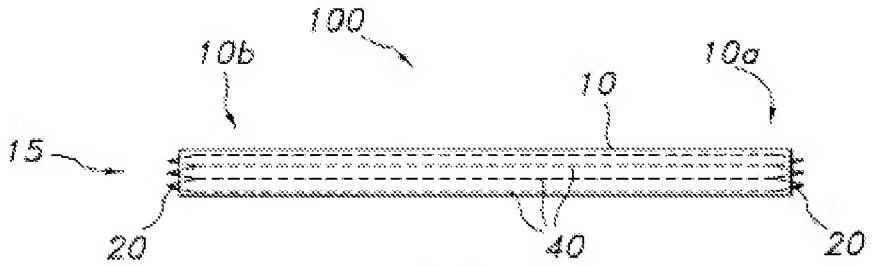

FIG 3